DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 3, 2015

CNMC Company Incorporated
% Mr. Thomas Kraus
Vice President R&D
865 Easthagen Drive
NASHVILLE TN 37217

Re: K150265
Trade/Device Name: Model 206 Electrometer/Dosimeter
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 14, 2015
Received: August 17, 2015

Dear Mr. Kraus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150265

Device Name
Model 206 Electrometer/ Dosimeter

Indications for Use *(Describe)*
The CNMC Model 206 is a medical dosimeter, or medical electrometer that is capable of performing measurements of diagnostic and therapeutic amounts of ionizing radiation when an appropriate ionization chamber or diode dosimeter is connected. These instruments are used exclusively by qualified personnel, typically medical physicists, for the calibration and quality control of medical equipment that produces ionizing radiation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

a Best Medical International company

510(k) Premarket Notification Summary

CNMC Model 206 Dosimeter/Electrometer

Submitter:	CNMC Company Incorporated 865 Easthagen Drive Nashville, Tennessee 37217
Contact:	Thomas Kraus Vice President R&D 615-391-3076 tkraus@cnmcco.com
Date:	August 24, 2015
Trade Names:	Model 206 Electrometer/ Dosimeter
Common Name:	Medical dosimeter, electrometer
Classification Name:	Medical charged-particle radiation therapy system (21 CFR 892.5050)
Classification:	Class II
Product Code:	IYE
Substantial Equivalence:	The CNMC Model 206 is substantially equivalent to the Sun Nuclear Model 1010/206 – K002444.
Description and Use:	The CNMC Model 206 is a medical dosimeter, or medical electrometer that is capable of performing measurements of diagnostic and therapeutic amounts of ionizing radiation when an appropriate ionization chamber or diode dosimeter is connected. These instruments are used exclusively by qualified personnel, typically medical physicists, for the calibration and quality control of medical equipment that produces ionizing radiation.
Intended Use:	The CNMC Model 206 is a dosimetry electrometer intended for measuring the output charge of an Ionization chamber or dosimetry diode that is used in a radiotherapy beam.

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com

Similarities/Differences of the CNMC Model 206 electrometer to their predicate device:

	Model 206	**Model 1010/206** K002444
How the device is used.	Dosimetry electrometer is used for measuring the output charge of an ion chamber in a radiotherapy beam. In addition device is intended for measurements with ion chamber or diode detectors as recommended during periodic QA testing.	Dosimetry electrometer is used for measuring the output charge of an ion chamber in a radiotherapy beam. In addition device is intended for measurements with ion chamber or diode detectors as recommended during periodic QA testing
Intended use	Radiation dosimetry	Radiation dosimetry
Detectors	ion chambers, diodes	ion chambers, diodes
Microprocessor controlled	no	no
External computer	Not required	Not required
Charge:		
Range	0.0001 pC to 1999.9 nC	0.0001 pC to 1999.9 nC
Resolution	10 fC	10 fC
Current:		
Range	0.001 pA to 1999.9 uA.	0.001 pA to 1999.9 uA.
Resolution	1 fA	1 fA
Bias voltage	-300/-150 to +300/+150	-300/-150 to +300/+150
Leakage Current	< 5 fA	< 5 fA
Power Supply	Six “D” Cell batteries	Six “D” Cell batteries
Battery Operation	Yes	Yes
RS 232 Interface	No	No
Chamber Library	No	No
Air Density Correction	No	No
Measuring Units	R, Gy, C, A, h, min, s	R, Gy, C, A, h, min, s
Display	Multifunction LCD	Multifunction LCD
Long Term Stability	± 0.1% per year	± 0.1% per years
Connector Type	Triaxial TNC, BNC	Triaxial TNC, BNC

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com

Conclusion: The model 206 is substantially equivalent to the predicate device for the following reasons:

1. The indication for use of the Model 206 is exactly the same as the predicate device.
2. The units are of identical design.
3. The Model 206 and the predicate device are tested to the same specifications.
4. The Model 206 and the predicate device uses the same vendors are for purchasing of the material for manufacturing
5. CNMC considers the Model 206 equivalent in all areas to the predicate device.

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com